35258s5

CLAIMS

1. A device for treatment of urinary stress incontinence, comprising:

at least one electrode, which is implanted in a pelvic muscle of a patient; and

a control unit, which receives signals indicative of abdominal stress in the patient and responsive thereto applies an electrical waveform to the electrode which stimulates the muscle to contract, so as to inhibit involuntary urine flow through the patient's urethra due to the stress.

2. A device according to claim 1, wherein the signals comprise electromyographic signals received from the at least one electrode.

3. A device according to claim 2, and comprising a switch between the electrode and an input of the control unit, which switch is opened when the electrical waveform is applied so as to prevent feedback from the electrode to the input.

4. A device according to claim 1, wherein the control unit comprises a processor, which analyzes the signals so as to determine when an involuntary urine flow is likely, whereupon the waveform is applied.

5. A device according to claim 4, wherein the processor distinguishes between signals indicative of an involuntary urine flow and signals indicative of voluntary voiding by the patient.

6. A device according to claim 5, wherein the processor gathers information regarding the signals over an extended period and analyzes the information to find a pattern characteristic of the patient, for use in determining when an involuntary urine flow is likely.

7. A device according to claim 6, wherein the pattern comprises a time-varying threshold to which a level of the signals is compared.

8. A device according to claim 5, wherein the processor distinguishes between the signals indicative of an involuntary urine flow and the signals indicative of voluntary voiding by the patient responsive to a rate of change of the signals.

9. A device according to claim 4, wherein the processor analyzes the signals at a sample rate substantially greater than 1000 Hz.

10. A device according to claim 4, wherein the processor's analysis is performed on substantially non-rectified data.

11. A device according to claim 4, wherein the processor analyzes the signals using spectral analysis.

12. A device according to claim 11, wherein the spectral analysis is performed by the processor on substantially non-rectified data.

13. A device according to claim 4, wherein the processor is programmable to vary one or more parameters associated with the application of the waveform.

14. A device according to claim 13, and comprising a wireless receiver, which receives data for programming the processor from a programming unit outside the patient's body.

15. A device according to claim 4, wherein the processor comprises a first processor, which analyzes the signals substantially continuously at a low data analysis rate, and a second processor, which is actuated by the first processor to analyze the signals at a high data analysis rate when the first processor determines that involuntary urine flow is likely to occur.

16. A device according to claim 15, and comprising a queue, in which the signals are stored before the second processor is actuated, and from which queue signals received by the control unit prior to actuation of the second processor are passed to the second processor for analysis.

17. A device according to claim 1, wherein the at least one electrode comprises a single unipolar electrode.

18. A device according to claim 1, wherein the at least one electrode comprises a pair of bipolar electrodes.

19. A device according to claim 1, wherein the at least one electrode comprises a flexible intra-muscular electrode.

20. A device according to claim 1, and comprising a physiological sensor coupled to the patient's bladder, which sensor provides at least some of the signals to the control unit.

21. A device according to claim 20, wherein the sensor comprises a pressure sensor.

22. A device according to claim 20, wherein the sensor comprises an acceleration sensor.

23. A device according to claim 20, wherein the sensor comprises an ultrasound transducer.

24. A device according to claim 1, wherein the control unit receives signals indicative of a fill level of the patient's bladder and, responsive to the signals, does not apply the electrical waveform when the fill level of the bladder is low, even when signals are received indicative of abdominal stress.

25. A device according to claim 1, wherein the at least one electrode and the control unit are implanted in the body of the patient.

26. A device according to claim 25, wherein the control unit comprises a rechargeable power source.

27. A device according to claim 26, wherein the power source is recharged by inductive energy transfer, substantially without electrical contact between the control unit and any object outside the patient's body.

28. A device according to claim 1, wherein the pelvic muscle comprises the levator ani muscle.

29. A device according to claim 1, wherein the pelvic muscle comprises the urethral sphincter muscle.

30. A device according to claim 1, wherein the pelvic muscle is adjacent to the urethral sphincter muscle.

31. A device for treatment of urinary incontinence in a patient, comprising:

a sensor, which is coupled to generate a signal responsive to a fill level of the patient's bladder; and

a control unit, which receives and analyzes the signal from the sensor so as to determine a fill level of the bladder and responsive thereto applies stimulation to a pelvic muscle of the patient, so as to inhibit involuntary flow of urine through the patient's urethra when the fill level of the bladder is above a threshold level.

32. A device according to claim 31, wherein the control unit receives a further signal indicative of abdominal stress and applies the stimulation to the pelvic muscle responsive to the stress except when the fill level of the bladder is below the threshold level.

33. A device according to claim 32, wherein the sensor comprises an electrode, which is placed in electrical contact with the pelvic muscle of the patient to receive an electromyogram signal therefrom indicative of the stress and of the fill level.

35258s5

34. A device according to claim 31, and comprising an electrode, which is placed in electrical contact with the pelvic muscle of the patient, and wherein the control unit applies an electrical waveform to the electrode so as to stimulates the muscle to contract, thereby inhibiting the involuntary flow of urine.

35. A device according to claim 31, wherein the sensor comprises a pressure sensor.

36. A device according to claim 31, wherein the sensor comprises an ultrasound transducer.

37. A device for treatment of urinary stress incontinence, comprising:

at least one electrode, which is placed in electrical contact with a pelvic muscle of a patient; and

a control unit, which receives electromyogram signals from the electrode indicative of abdominal stress in the patient, and which determines a threshold signal level that varies over time responsive to a condition of the patient, and which, responsive to a transient increase in the electromyogram signal above the threshold level, applies an electrical waveform to the electrode which stimulates the muscle to contract, so as to inhibit involuntary urine flow through the patient's urethra due to the stress.

38. A device according to claim 37, wherein the threshold signal level varies over time responsive to temporal variation of a mean value of the electromyogram signals.

39. A device according to claim 37, wherein the threshold signal level increases responsive to time elapsed since the patient last passed urine.

40. A device according to claim 37, wherein the threshold signal level increases responsive to an increase in a fill level of the patient's bladder.

41. A device for treatment of urinary stress incontinence, comprising:

at least one electrode, which is placed in electrical contact with a pelvic muscle of a patient; and

a control unit, which receives electromyogram signals from the electrode and, responsive to a rate of change of the signals indicative of a possible involuntary urine flow, applies an electrical waveform to the electrode which stimulates the muscle to contract, so as to inhibit the involuntary urine flow.

42. A device according to claim 41, wherein when the rate of change is below a threshold rate, the control unit withholds the waveform so as to allow voluntary voiding.

43. A device for treatment of urinary stress incontinence, comprising:

at least one electrode, which is placed in electrical contact with a pelvic muscle of a patient; and

a control unit, which receives signals indicative of impending urine flow, and distinguishes signals indicative of an involuntary urine flow from signals indicative of voluntary voiding by the patient, and responsive thereto applies an electrical waveform to the electrode which stimulates the muscle to contract, so as to inhibit involuntary urine flow.

44. A device according to claim 43, wherein the control unit gathers information regarding the signals over an extended period and analyzes the information to find a pattern characteristic of the patient, for use in determining when involuntary urine flow is likely.

45. A device according to claim 44, wherein the pattern comprises a time-varying threshold to which a level of the signals is compared.

46. A device according to claim 43, wherein the control unit distinguishes between the signals indicative of an

involuntary urine flow and the signals indicative of voluntary voiding by the patient responsive to a rate of change of the received signals.

47. A device according to claim 43, wherein the control unit distinguishes between the signals indicative of an involuntary urine flow and the signals indicative of voluntary voiding, substantially without application of an input to the control unit from outside the patient's body.

48. A device for treatment of urinary stress incontinence, comprising:

at least one electrode, which is placed in electrical contact with a pelvic muscle of a patient; and

a control unit, which receives at a sample rate substantially greater than 1000 Hz signals indicative of abdominal stress in the patient, analyzes the signals so as to determine when an involuntary urine flow is likely and responsive thereto applies an electrical waveform to the electrode which stimulates the muscle to contract, so as to inhibit involuntary urine flow through the patient's urethra due to the stress.

49. A device according to claim 48, wherein the control unit analyzes the signals so as to distinguish between signals indicative of an involuntary urine flow and signals indicative of voluntary voiding by the patient.

50. A device for treatment of urinary stress incontinence, comprising:

at least one electrode, which is placed in electrical contact with a pelvic muscle of a patient;

a first processor, which receives signals indicative of abdominal stress in the patient and analyzes the signals substantially continuously at a low data analysis rate; and

a second processor, which, responsive to a determination by the first processor that involuntary

urine flow is likely to occur, is actuated by the first processor to analyze the signals at a high data analysis rate and, responsive to the analysis at the high data rate, applies an electrical waveform to the electrode which stimulates the muscle to contract, so as to inhibit involuntary urine flow.

51. A device according to claim 50, and comprising a queue, in which the signals are stored before the second processor is actuated, and from which queue signals received by the first processor prior to actuation of the second processor are passed to the second processor for analysis.

52. A method for treatment of urinary stress incontinence of a patient, comprising:

placing an electrode in electrical contact with a pelvic muscle of the patient;

receiving a signal from the patient's body indicative of abdominal stress;

analyzing the received signal to distinguish between a signal indicating that involuntary urine flow is likely and another signal indicative of voluntary voiding; and

responsive to the analysis, applying an electrical waveform to the electrode, which stimulates the muscle to contract so as to inhibit involuntary urine flow.

53. A method according to claim 52, wherein distinguishing between the signals comprises gathering information regarding the received signal over an extended period and analyzing the information to detect a pattern characteristic of the patient, for use in determining when an involuntary urine flow is likely.

54. A method according to claim 53, wherein the pattern comprises a time-varying threshold to which a level of the received signal is compared.

55. A method according to claim 52, wherein distinguishing between the signals comprises

distinguishing responsive to a rate of change of the received signal.

56. A method for treatment of urinary stress incontinence of a patient, comprising:

placing an electrode in electrical contact with a pelvic muscle of the patient;

receiving at a sample rate substantially greater than 1000 Hz signals indicative of abdominal stress;

analyzing the signals so as to determine when an involuntary urine flow is likely; and

responsive to the analysis, applying an electrical waveform to the electrode, which stimulates the muscle to contract so as to inhibit involuntary urine flow.

57. A method according to claim 56, wherein analyzing comprises distinguishing between a signal indicating that involuntary urine flow is likely and another signal indicative of voluntary voiding.

58. A method for treatment of urinary stress incontinence of a patient, comprising:

implanting an electrode in a pelvic muscle of the patient;

receiving a signal from the patient's body indicative of abdominal stress; and

responsive to the signal, applying an electrical waveform to the electrode, which stimulates the muscle to contract so as to inhibit involuntary urine flow.

59. A method according to 58, wherein the pelvic muscle comprises the levator ani muscle.

60. A method according to claim 58, wherein the pelvic muscle comprises the urethral sphincter muscle.

61. A method according to claim 58, wherein implanting the electrode comprises implanting an electrode in proximity to the urethral sphincter muscle.

62. A method according to claim 58, wherein applying the waveform comprises applying a waveform to the electrode in a unipolar mode.

63. A method according to claim 58, wherein implanting the electrode comprises placing at least two electrodes in electrical contact with the muscle, and wherein applying the waveform comprises applying a waveform between the electrodes in a bipolar mode.

64. A method according to claim 58, wherein receiving the signal comprises receiving an electromyographic signal.

65. A method according to claim 58, wherein receiving the signal comprises receiving a signal indicative of pressure on the patient's bladder.

66. A method according to claim 58, wherein receiving the signal comprises receiving a signal indicative of motion of the patient's bladder.

67. A method according to claim 58, and comprising receiving a signal indicative of a fill level of the patient's bladder, wherein applying the electrical waveform comprises applying a waveform responsive to the fill level.

68. A method according to claim 67, wherein applying the waveform responsive to the fill level comprises withholding application of the waveform when the fill level is low notwithstanding the signal received indicative of abdominal stress.

69. A method according to claim 58, wherein applying the waveform comprises analyzing the signal to determine when an involuntary urine flow is likely, and applying a waveform dependent on the determination.

70. A method according to claim 69, wherein analyzing the signal comprises analyzing substantially non-rectified data.

71. A method according to claim 69, wherein analyzing the signal comprises performing a spectral analysis.

72. A method according to claim 71, wherein performing the spectral analysis comprises performing the spectral analysis on substantially non-rectified data.

73. A method according to claim 69, wherein analyzing the signal comprises distinguishing between a signal indicating that the involuntary urine flow is likely and another signal indicative of voluntary voiding.

74. A method according to claim 73, wherein distinguishing between the signals comprises gathering information regarding the signals over an extended period and analyzing the information to detect a pattern characteristic of the patient, for use in determining when an involuntary urine flow is likely.

75. A method according to claim 74, wherein analyzing the information comprises finding a time-varying threshold to which a level of the signals is compared.

76. A method according to claim 73, wherein distinguishing between the signals comprises distinguishing responsive to a rate of change of the signals.

77. A method according to claim 69, wherein analyzing the signal comprises analyzing signals at a sample rate substantially greater than 1000 Hz.

78. A method according to claim 58, wherein applying the waveform comprises varying a parameter of the waveform selected from a group including amplitude, frequency, duration, wave shape and duty cycle.

79. A method according to claim 58, wherein applying the waveform comprises applying a pulse burst.

80. A method for treatment of urinary incontinence in a patient, comprising:

receiving a signal indicative of a fill level of the patient's bladder; and

responsive to the signal, applying stimulation to a pelvic muscle of the patient, so as to inhibit involuntary flow of urine through the patient's urethra when the fill level of the bladder is above a threshold level.

81. A method according to claim 80, and comprising receiving a further signal indicative of abdominal stress, wherein applying the stimulation comprises applying stimulation responsive to the stress except when the fill level of the bladder is below the threshold level.

82. A method according to claim 81, wherein receiving the signal comprises receiving an electromyogram signal from an electrode in contact with the pelvic muscle, wherein the signal is indicative of the stress and of the fill level.

83. A method according to claim 80, wherein applying the stimulation comprises applying an electrical waveform to an electrode in contact with the pelvic muscle, thereby stimulating the muscle to contract and inhibiting the involuntary flow of urine.

84. A method according to claim 80, wherein receiving the signal comprises receiving a pressure signal.

85. A method according to claim 80, wherein receiving the signal comprises receiving an ultrasound signal.

86. A method for treatment of urinary stress incontinence, comprising:

placing an electrode in electrical contact with a pelvic muscle of a patient;

receiving electromyogram signals from the electrode indicative of abdominal stress in the patient;

determining a threshold level of the signals that varies over time responsive to a condition of the patient; and

responsive to a transient increase in the signals above the threshold level, applying an electrical waveform to the electrode which stimulates the muscle to contract, so as to inhibit involuntary urine flow through the patient's urethra due to the stress.

87. A method according to claim 86, wherein determining the threshold level comprises determining a level that varies over time responsive to temporal variation of a mean value of the electromyogram signals.

88. A method according to claim 86, wherein determining the threshold level comprises increasing the threshold level responsive to time elapsed since the patient last passed urine.

89. A method according to claim 86, wherein determining the threshold level comprises increasing the threshold level responsive to an increase in a fill level of the patient's bladder.

90. A method for treatment of urinary stress incontinence, comprising:

placing an electrode in electrical contact with a pelvic muscle of a patient;

receiving electromyogram signals from the electrode indicative of abdominal stress in the patient;

determining a rate of change of the signals; and

responsive to the rate of change, applying an electrical waveform to the electrode which stimulates the muscle to contract, so as to inhibit an involuntary urine flow.

91. A method according to claim 90, wherein applying the waveform comprises applying a waveform when the rate of change is above a threshold rate, and comprising

35258s5

withholding the waveform when the rate of change is below the threshold rate so as to allow voluntary voiding.